

ORIGINAL
IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

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UNITED STATES OF AMERICA
ex rel. Brian Berger and Janice Delp

STATE OF TEXAS
ex rel. Brian Berger and Janice Delp;

Plaintiffs,

VS.

BAYLOR UNIVERSITY MEDICAL CENTER
at DALLAS, BAYLOR HEALTH CARE
SYSTEM, HEALTHTEXAS PROVIDER
NETWORK, and TEXAS ONCOLOGY,
P.A.;

Defendants.

CIVIL NO. _____

3-10 CV-1103 G

**FILED IN CAMERA AND
UNDER SEAL**

SEALED

JURY TRIAL DEMANDED

**ORIGINAL COMPLAINT OF RELATORS
BRIAN BERGER AND JANICE DELP**

1. The United States of America and the State of Texas, by and through *qui tam* relators Brian Berger and Janice Delp, bring this action under 31 U.S.C. §§ 3729–3732 (the “False Claims Act”) to recover all damages, penalties, and other remedies established by the False Claims Act on behalf of the United States and themselves and would show the following:

I. Introduction

2. At the very heart of this case is the Defendants’ disregard for the safety and well-being of their patients—patients who, in hopes of surviving cancer, agree to undergo extremely powerful forms of radiation therapy. By their very natures, these forms of radiation therapy involve inherent risks—most notably the risk of a radiation overdose and the risk that the radiation will be delivered to the wrong area. Although the Defendants’ patients believe that

their lives are in the hands of caring, capable physicians during these highly complex and risky procedures, the radiation is actually delivered without the required physician supervision. In fact, in order to maximize their own profits at the expense of patient safety, the Defendants both allow and encourage the physicians who are supposed to be supervising the radiation therapy—the radiation oncologists—to perform other duties and procedures in other places while their patients are being exposed to potentially lethal levels of radiation.

3. Baylor Radiosurgery Center, located at Baylor University Medical Center at Dallas (“Baylor University Medical Center”), is a state-of-the-art radiosurgical suite that performs Gamma Knife and CyberKnife stereotactic radiosurgery—highly-advanced, non-invasive forms of radiation therapy. Because of the inherent risks involved with the medical use of radiation, Gamma Knife and CyberKnife procedures are heavily regulated by the Nuclear Regulation Commission (“NRC”) and the Centers for Medicare & Medicaid Services (“CMS”), especially with respect to physician supervision.

4. In order to be licensed to perform Gamma Knife procedures, the NRC requires an authorized user (i.e., a radiation oncologist) and a medical physicist to be physically present throughout the procedure. CyberKnife, while not regulated by the NRC, is regulated by the State of Texas, which imposes supervision requirements in connection with each CyberKnife registration that it grants. Baylor University Medical Center’s CyberKnife registration with the State of Texas requires a radiation oncologist and a medical physicist to be immediately available throughout the course of the procedure.

5. As a condition of payment, Medicare, Texas Medicaid, and CHAMPUS/TRICARE require both Gamma Knife and CyberKnife procedures to be directly supervised by a qualified physician—meaning that a clinically appropriate physician (i.e., a

radiation oncologist) must be immediately available to step in and perform the procedure if necessary.

6. Since Baylor Radiosurgery Center was founded in 2004, however, HealthTexas and Texas Oncology, P.A. (“TOPA”), both physicians’ groups whose members treat patients at Baylor Radiosurgery Center, as well as Baylor University Medical Center have systematically failed to ensure that these highly complex and risky procedures are properly supervised. Although the lack of proper supervision puts their patients at risk, Baylor University Medical Center has a financial motive for turning a blind eye to the lack of physician supervision: TOPA patient referrals.

7. TOPA physicians lease space from Baylor University Medical Center in Sammons Cancer Center, where they treat TOPA patients. TOPA radiation oncologists also perform stereotactic radiosurgery procedures on TOPA patients at Baylor Radiosurgery Center. Because Baylor University Medical Center owns the equipment at Baylor Radiosurgery Center, it receives the reimbursement for the technical component of each service performed at the radiosurgery center—including the procedures performed by TOPA physicians. Although the TOPA physicians receive the reimbursement for the professional component of each service they perform at Baylor Radiosurgery Center, they have repeatedly complained about the stringent supervision requirements. Because TOPA physicians can receive reimbursement for both the professional and technical components for their services at their offices in Sammons Cancer Center, they leave Baylor Radiosurgery Center during their stereotactic radiosurgery procedures in order to treat TOPA patients at their offices.

8. Rather than mandating compliance with the supervision requirements, Baylor University Medical Center tolerates the supervision violations (by both HealthTexas and TOPA

physicians) in order to induce TOPA physicians to refer patients. Importantly, Baylor University Medical Center not only relies on TOPA to refer patients to Baylor Radiosurgery Center, but also relies on TOPA's referral of chemotherapy and patients for inpatient hospital services. TOPA financially benefits from this arrangement as well because it allows them to double-bill: while a TOPA radiation oncologist is billing the professional component of a stereotactic radiosurgery procedure he is allegedly performing at Baylor Radiosurgery Center, the same TOPA radiation oncologist is billing for another procedure performed at Sammons Cancer Center at the exact same time.

9. Relators, Dr. Brian Berger (a radiation oncologist) and Janice Delp (a radiation therapist), repeatedly brought the lack of proper supervision during stereotactic radiosurgery procedures to the attention of Baylor management, including Joel Allison, the President and Chief Executive Officer of Baylor Health Care System, John McWhorter, the President of Baylor University Medical Center and the Senior Vice President of Baylor Health Care System, and Gail Maxwell, the Vice President of Administration at Baylor University Medical Center. The concerns for patient safety voiced by Dr. Berger and Delp, however, were ignored by all levels of Baylor management.

10. Knowing that they have failed to provide proper supervision of Gamma Knife and CyberKnife procedures, Baylor University Medical Center, HealthTexas, and TOPA nevertheless continued to bill and receive reimbursement for these services.

11. In addition to their repeated violations of physician supervision requirements, the Defendants also engaged in at least four additional categories of fraud. First, the Defendants overbilled government health insurance programs for CyberKnife treatments by fraudulently inflating the number of calculations performed. Second, the Defendants engaged in a scheme to

bill government health insurance programs for certain services individually when CMS required these services to be billed together; this type of scheme is often referred to as “unbundling.” Third, Baylor created fake CyberKnife treatment plans that they never intended to use on patients for the sole purpose of billing additional planning codes. Finally, Baylor University Medical Center paid illegal kickbacks to TOPA in exchange for patient referrals. TOPA responded to this inducement by referring patients to Baylor University Medical Center, a violation of the Stark Act.

12. All of these categories of knowing false and fraudulent conduct have led to the submission of false and fraudulent claims against state and federal government health insurance programs in violation of the Texas and Federal False Claims Acts.

II. Parties

13. Relator Dr. Brian Berger (“Dr. Berger”) is a citizen of the United States and a resident of the State of Texas.

14. Relator Janice Delp (“Delp”) is a citizen of the United States and a resident of the State of Texas.

15. Defendant Baylor University Medical Center at Dallas is a corporation incorporated in the State of Texas and may be served through its registered agent, CT Corporation System, 350 North Saint Paul Street, Dallas, Texas 75201.

16. Defendant Baylor Health Care System is a corporation incorporated in the State of Texas and may be served through its registered agent, CT Corporation System, 350 North Saint Paul Street, Dallas, Texas 75201.

17. Defendant HealthTexas Provider Network (“HealthTexas”) is a corporation incorporated in the State of Texas and may be served through its registered agent, CT Corporation System, 350 North Saint Paul Street, Dallas, Texas 75201.

18. Defendant Texas Oncology, P.A. (“TOPA”), a Texas corporation, is a physician group made up of almost exclusively medical and radiation oncologists, such as Dr. Scott Cheek and Dr. Barry Wilcox, devoted exclusively to cancer treatment and cancer research. TOPA leases office space from Baylor University Medical Center in the Baylor Charles A. Sammons Cancer Center (“Sammons Cancer Center”). Sammons Cancer Center, which is part of Collins Hospital, is a specialty center dedicated to cancer treatment and research. Radiation oncologists employed by TOPA treat stereotactic radiosurgery patients at Baylor Radiosurgery Center. In addition to performing stereotactic radiosurgery procedures at Baylor Radiosurgery Center, TOPA radiation oncologists also treat patients at their offices in Sammons Cancer Center. TOPA may be served through its registered agent, John Ernest Sims, 12221 Merit Drive, Suite 500, Dallas, Texas 75251.

III. Respondeat Superior and Vicarious Liability

19. Any and all acts alleged herein to have been committed by any or all of the Defendants were committed by said Defendants’ officers, directors, employees, representatives, or agents, who at all times acted on behalf of their respective Defendant(s) and within the scope and course of their employment for the purpose of benefitting their employers.

20. Defendants Baylor University Medical Center, Baylor Health Care System (hereinafter referred to collectively as “Baylor”), and HealthTexas are related entities sharing common employees, offices, and business names, such that they are jointly and severally liable under legal theories of respondeat superior. Further, the past, present, and continuing relations

and dealings by and between these related entities are so inextricably intertwined that for purposes of this suit, they can and should be considered as a single entity at law and equity.

21. Baylor Health Care System is the parent company of Baylor University Medical Center and HealthTexas. Baylor Health Care System was formally established in 1981 with Baylor University Medical Center as its flagship hospital and corporate headquarters. Baylor University Medical Center, which is wholly owned and operated by Baylor Health Care System, is one of the largest non-profit medical centers in the nation. With 1,025 licensed beds and 1,225 physicians, Baylor University Medical Center spans more than 120 acres and encompasses six connecting hospitals: (1) A. Webb Roberts Hospital (“Roberts Hospital”), (2) Carr P. Collins Hospital (“Collins Hospital”), (3) Erik and Margaret Johnsson Medical and Surgical Hospital, (4) George W. Truett Memorial Hospital (“Truett Hospital”), (5) Baylor Jack and Jane Hamilton Heart and Vascular Hospital, and (6) Karl and Esther Hoblitzelle Memorial Hospital (“Hoblitzelle Hospital”). *See* Baylor University Medical Center Campus Map, attached as Exhibit 1.

22. Baylor Radiosurgery Center, which is located on the first floor of Hoblitzelle Hospital, is the first surgical suite in Texas dedicated primarily to Gamma Knife and CyberKnife procedures. Baylor Radiosurgery Center is staffed by neurosurgeons, radiation oncologists, and other specialists who are members of the medical staff at Baylor University Medical Center. HealthTexas, a physician group affiliated with Baylor Health Care System, employs many of the physicians on staff at Baylor University Medical Center, including radiation oncologists who work at Baylor Radiosurgery Center, such as Dr. John O’Connor, and at one time, Dr. Berger.

23. Baylor Health Care System is a non-profit healthcare entity that provides inpatient, outpatient, and emergency medical services. Baylor Health Care System serves nearly

1.4 million patients each year and is comprised of twenty-five hospitals, twenty-one surgical centers, thirty-one satellite outpatient locations, four senior centers, and 131 HealthTexas physician clinics. For Fiscal Year 2009, Baylor Health Care System reported having 3,423 licensed beds, 4,546 physicians, \$3.9 billion in total assets, and \$3.4 billion in total operating revenue. The following Baylor Health Care System facilities are located at Baylor University Medical Center: (1) Baylor Institute for Rehabilitation, (2) Baylor Institute of Immunology Research, (3) Baylor Research Institute, (4) Baylor Specialty Hospital, (5) Baylor Tom Landry Health and Wellness Center, (6) Our Children's House at Baylor, and (7) Kimberly H. Courtwright and Joseph W. Summers Institute of Metabolic Disease. Furthermore, Baylor University Medical Center, Baylor Health Care System, and HealthTexas share officers and directors. For example, the current President of Baylor University Medical Center, John B. McWhorter, III, is also a Senior Vice President of Baylor Health Care System. Bill Roberts, the President of HealthTexas, is also a Senior Vice President of Baylor Health Care System.

IV. Jurisdiction and Venue

24. Jurisdiction and venue are proper in this Court pursuant to the False Claims Act (31 U.S.C. § 3732(a)) because Relators' claims seek remedies on behalf of the United States for multiple violations of 31 U.S.C. § 3729 in the United States by all or any one of the Defendants, some of which occurred in the Northern District of Texas, and because all or any one of the Defendants transact other business within the Northern District of Texas.

V. Overview of Stereotactic Radiosurgery and the Risks Associated with Radiation Therapy

A. Stereotactic Radiosurgery

25. Stereotactic radiosurgery is a highly precise form of radiation therapy that serves as an alternative to invasive surgery to treat tumors—especially for tumors and blood vessel

abnormalities located deep within or close to vital areas of the brain. Stereotactic radiosurgery delivers a high dose of precisely-targeted radiation using highly focused gamma-ray or x-ray beams to a specific area of the body. Because stereotactic radiosurgery is non-invasive, it is performed on an outpatient basis.

26. Like other radiation treatments, stereotactic radiosurgery does not remove tumors; rather, the radiation damages the DNA of the tumors, causing the cells to lose their ability to reproduce. Following stereotactic radiosurgery treatment, tumors usually shrink over a period of eighteen months to two years. Because malignant or metastatic tumors are fast-growing cells, these tumors tend to shrink more rapidly.

27. Different kinds of stereotactic radiosurgery equipment exist and each manufacturer of radiosurgery equipment gives its system a brand name. Gamma Knife and CyberKnife, for example, are certain brands of stereotactic radiosurgery systems. Each system differs in the manner in which planning is done and radiation is delivered. Gamma Knife, a cobalt-60 based machine,¹ uses 201 beams of highly focused gamma rays that are aimed at the target region. Gamma Knife is ideal for treating small- or medium-sized tumors, but is dedicated only to treatment of the brain. A typical Gamma Knife treatment may last anywhere from one to four hours.

28. CyberKnife, a linear accelerator machine, is capable of treating tumors throughout the brain and body by delivering high-energy x-rays, also known as photons. CyberKnife can perform radiosurgery on large tumors in a single session or during multiple sessions. Providing

¹ Cobalt-60 is a radioactive isotope of cobalt. Cobalt-60 is commonly used for radiosurgery in hospitals for the precise treatment of tumors and other deformities. See U.S. Environmental Protection Agency, *Radiation Protection: Cobalt*, <http://www.epa.gov/rpdweb00/radionuclides/cobalt.html> (last visited Mar. 24, 2010).

treatment over multiple sessions is known as “fractionated stereotactic radiotherapy”² and each session is referred to as a “fraction.”

B. The Use of Medical Radiation: Risks and Consequences

29. Americans currently receive far more medical radiation than ever before; in fact, the average lifetime dose of diagnostic radiation has increased sevenfold since 1980.³ Although radiation therapy often constitutes an effective treatment for tumors, the use of radiation as a potential cure for cancer carries significant—and sometimes fatal—risks. The risks associated with radiation therapy continue to increase despite the advancements in radiation therapy technology. In fact, according to Dr. John Feldmeir, a radiation oncologist at the University of Toledo and a leading authority on the treatment of radiation injuries, approximately one in twenty patients receiving radiation therapy will suffer injuries.⁴

(1) The Risks Associated with Radiation Therapy

30. The most serious risk associated with radiation therapy is the risk of a radiation overdose. Radiation overdoses may be caused by machine malfunctions or may result from violations of safety regulations. The consequences of a radiation overdose can range from mild skin burns to organ failure and even death. An overdose may also damage the cells lining small blood vessels, depriving the skin and soft tissue of nourishment and resulting in wounds that resist healing. Additionally, once the soft tissue is injured as a result of an overdose, bone death is common.

² Stereotactic “radiosurgery” involves treatment given in a single session. If given in multiple sessions, however, the treatment is referred to as stereotactic “radiotherapy.”

³ Walt Bogdanich, *The Radiation Boom: Radiation Offers New Cures, and Ways to do Harm*, N.Y. TIMES, Jan. 24, 2010, available at <http://www.nytimes.com/2010/01/24/health/24radiation.html?pagewanted=all> (attached as Exhibit 2).

⁴ *Id.*

31. In 2005, a Florida hospital disclosed that seventy-seven brain cancer patients received fifty percent more radiation than prescribed because one of its linear accelerators had been programmed incorrectly for nearly a year.⁵ In 2009, Cedars-Sinai Medical Center in Los Angeles disclosed that it had accidentally exposed more than 260 patients to eight times the normal dose of radiation for CT brain scans over an eighteen month period.⁶

32. Despite their prevalence, studies show that radiosurgery accidents are chronically unreported. In January 2010, The New York Times reported the results of its investigation into 621 radiation mistakes that occurred in New York State between 2001 and 2008.⁷ In 284 of the cases, radiation used for a particular medical treatment missed all or part of its intended target or treated the wrong body part entirely. Of these cases, fifty patients received radiation intended for someone else, including one brain cancer patient who received radiation intended for breast cancer. Another patient with stomach cancer was mistakenly treated for prostate cancer.⁸

33. Overall, the New York Times investigation focused primarily on two cases that profoundly illustrate the true nature of the risks and consequences associated with medical radiation.⁹ In early 2005, Scott Jerome-Parks was diagnosed with a cancerous tumor, found at the base on his tongue. After discussing his treatment options with his doctor, Mr. Jerome-Parks opted to have stereotactic radiosurgery delivered by a linear accelerator. Mr. Jerome-Parks' first four radiation treatments were delivered without incident, but his doctor wanted to re-work the radiation plan. On the morning of March 14, 2005, the medical physicist assigned to Mr. Jerome-Parks' case revised the treatment plan using the linear accelerator's software.

⁵ *Id.*

⁶ Andrew Zajac and Alan Zarembo, *Radiation Worries Prompt FDA to Regulate Medical Scanners*, HOUSTON CHRON., Feb. 10, 2010, at A3.

⁷ Walt Bogdanich, *The Radiation Boom: Radiation Offers New Cures, and Ways to do Harm*, N.Y. TIMES, Jan. 24, 2010, available at <http://www.nytimes.com/2010/01/24/health/24radiation.html?pagewanted=all>.

⁸ *Id.*

⁹ *Id.*

34. Shortly after 11:00 a.m., as the medical physicist was trying to save the new treatment plan, the computer began seizing up and displaying error messages, which asked whether the physicist wanted to save the changes to the treatment plan before the program aborted; the physicist answered yes. At 12:24 p.m., the doctor approved the new treatment plan, and Mr. Jerome-Parks was prepped for his treatment. At 12:57 p.m., just six minutes after yet another computer crash, the first radiation treatment under the new treatment plan began.

35. Friends and family of Mr. Jerome-Parks immediately became concerned when they observed the severe swelling of Mr. Jerome Parks' head and neck following these two treatments. Only after this third treatment under the new plan, however, did the medical physicist check to see whether Mr. Jerome-Parks was being radiated correctly. The results of her investigation revealed that the multileaf collimeter—the device that was supposed to precisely focus the radiation on the tumor—was wide open. As a result, Mr. Jerome-Parks' neck, from the base of his skull to his larynx, had been exposed to seven times the amount of prescribed radiation.

36. After an investigation into the cause of the overdose, it was discovered that the linear accelerator's software had not saved the instructions for the collimeter. Importantly, this mistake could have easily been discovered by anyone monitoring the computer screen during the radiation treatment—the screen clearly indicated that the collimeter was wide open.

37. The three consecutive days of radiation left Mr. Jerome-Parks deaf, mostly blind, unable to swallow, nauseated, in severe pain, burned, with his teeth falling out, with ulcers in his mouth and throat, and, finally, unable to breathe. He died in 2007 at the age of 43.

38. Soon after the radiation overdose occurred, New York state officials cautioned hospitals to be extremely careful with linear accelerators. The same day the alert went out,

however, a 32-year-old breast cancer patient named Alexandra Jn-Charles absorbed the first of twenty-seven consecutive days of radiation overdoses.¹⁰ Each overdose constituted three times the prescribed dose of radiation.

39. The linear accelerator used to deliver Ms. Jn-Charles' radiation did not use a multileaf collimeter but instead used a simpler beam-modifying device called a wedge—a metallic block that serves as a filter. Although the radiation treatment seemed to be going well, towards the end of the therapy, Ms. Jn-Charles developed a sore on her chest. When Ms. Jn-Charles arrived for her twenty-eighth and final treatment, the radiation therapist took her to see a radiation oncologist. The only thing he told her was that she would not be receiving any more radiation and that she could go home.

40. Two weeks after Ms. Jn-Charles' last radiation treatment, the hospital decided to investigate the possible causes of her injuries. The investigation was short and revealed a deadly mistake: the linear accelerator's software was missing a vital command—to insert the wedge. Without the filter, Ms. Jn-Charles' treatment team had been mistakenly scalding her with three and half times the prescribed radiation dose in each and every session. As with Mr. Jerome-Parks, the fact that there was a mechanical error was clearly displayed on computer screens during the treatments. The error, however, went unnoticed.

41. The overdose resulted in a festering wound that would not heal. Despite sessions in a hyperbaric oxygen chamber and several reconstructive surgeries, the wound continued getting considerably worse. Meanwhile, her cancer returned with a vengeance. After several months of pain that was so intense that she considered suicide, Ms. Jn-Charles died.

42. The deadly consequences of radiation-related errors can be tempered—if not completely eliminated—by compliance with applicable safety standards and training

¹⁰ *Id.*

requirements. Indeed, stereotactic radiosurgery is heavily regulated in an attempt to ensure patient safety. The majority of these regulations focus on supervision requirements during stereotactic radiosurgery procedures as well and training and education requirements for those delivering the radiation. As demonstrated by the cases of Mr. Jerome-Parks and Ms. Jn-Charles, physicians with the proper training and education, *who properly supervise the procedures*, can save lives by catching errors that could likely prove deadly.

43. Physician supervision is especially important in Gamma Knife and CyberKnife cases. Because of the mathematics used to determine the appropriate stereotactic radiosurgery radiation dosage, any targeting error can result in the delivery of more than ten times the prescribed dose of radiation used in more traditional radiation therapy.

(2) *Minimizing Risks: The Stereotactic Radiosurgery Treatment Team*

44. Because of the risks involved with radiation therapy, stereotactic radiosurgery treatment involves a specialized team of medical professionals, including a radiation oncologist, neurosurgeon, medical physicist, radiation therapist, and nurse. The radiation oncologist heads the treatment team and manages the treatment. In doing so, the radiation oncologist outlines the targeted area(s) to be treated, decides on the appropriate radiation dose, approves the treatment plan, and interprets the results of the radiosurgical procedures.

45. The medical physicist's primary responsibility is to ensure that the patient receives the proper dose of radiation. The physicist, or a dosimetrist under the supervision of the physicist, uses special computer software to devise the treatment plan and is responsible for calculating the exposures and beam configuration to ensure that the targeted area(s) are treated at the prescribed dose.

46. A neurosurgeon often participates in the initial treatment decision-making. During a stereotactic radiosurgery procedure, a neurosurgeon may be responsible for placement and removal of the stereotactic head frame, in the case of Gamma Knife procedures, locating and specifying the radiation target (in concert with the radiation oncologist), participating in the plan development and approval of the final treatment plan, and ensuring that the patient is positioned correctly before treatment begins.

47. During the treatment phase for CyberKnife procedures, a highly-trained radiation therapist positions the patient on the treatment table and operates the machine from an adjacent radiation-protected area. The radiation therapist can observe the patient on a closed-circuit television and is able to communicate with the patient throughout the procedure. In the case of Gamma Knife, a radiation oncologist or the medical physicist positions the patient and operates the Gamma Knife machine. Like CyberKnife, during a Gamma Knife procedure, the radiation oncologist or medical physicist can observe the patient on a closed-circuit television and is able to communicate with the patient throughout the procedure.

C. Gamma Knife

48. By its very nature, Gamma Knife radiosurgery involves inherent radiation risks, including the risk of a radiation overdose and the risk that the radiation will be targeted on the wrong area of the brain. Because of these inherent risks, Gamma Knife radiosurgery is strictly regulated. As discussed in more detail *infra*, the most important regulation in terms of ensuring the safety of the patient during Gamma Knife treatment is the Nuclear Regulatory Commission's requirement that an authorized user (i.e. the radiation oncologist) and an authorized medical physicist be physically present during the treatment.

49. Once the treating physicians determine that a patient should receive Gamma Knife treatment, a planning sheet containing the patient's diagnosis, the anatomic site to be treated, imaging scans required, positioning of the patient, immobilization devices to be used, and other similar information is signed by the treating physicians. At this time, the patient is scheduled for a day long procedure, e.g. 6 a.m. to 6 p.m., although the procedure may only last part of the day. Gamma Knife treatment involves several steps, each of which are discussed in more detail below: (1) preparation and frame placement, (2) treatment planning, including simulation, and (3) treatment delivery.

(1) Gamma Knife Preparation and Frame Placement

50. Gamma Knife radiosurgery requires an aluminum head frame that weighs approximately six and half pounds, to be attached to the patient's skull. The neurosurgeon is required to be present to screw the box-shaped head frame to the patient's skull using specially designed pins. The radiation oncologist's presence is not required at this stage. Frame placement generally takes 30 to 45 minutes to perform.

51. The head frame serves two purposes: (1) it prevents the patient's head from moving until the treatment session is finished, and (2) it acts as reference for the Gamma Knife machine to ensure that the radiation beams are focused exactly where treatment is needed. Because the Gamma Knife's settings and calculations are keyed to the exact location of the patient's head within the frame, the patient must stay attached to the head frame until the entire treatment session is complete. For this reason, the Gamma Knife procedure occurs in a single session that can last from several hours to all day.

(2) *Gamma Knife Treatment Planning Phase*

52. Once the head frame is screwed into the patient's skull, the patient begins the first phase of the treatment planning phase—simulation/imaging. During this simulation/imaging phase of Gamma Knife treatment, a localizer box is attached to the frame, and the patient is taken to radiology to have imaging scans performed. This process may take anywhere from 45 minutes to two hours, depending on the image scanning to be performed. Generally, an MRI scan is performed on the patient to show the exact location of the tumor in relation to the head frame. In some cases, a computed tomography ("CT") scan and/or an angiogram may be performed in addition to, an MRI scan. Accurate imaging is absolutely essential to ensure that the patient receives radiation in only the appropriate areas.

53. After imaging is complete, the treating physicians review the images. The radiation oncologist, neurosurgeon, diagnostic radiologist, and physicists then collaborate to create the plan using the Gamma Knife treatment planning software to optimally irradiate the tumor and minimize radiation to surrounding normal tissues. This process may take from 30 minutes to several hours depending on the complexity of the case. Once a plan is developed and approved by the team, the radiation oncologist and neurosurgeon provide the physicist with a signed prescription for the treatment. The physicist verifies the prescription, and the Gamma Knife treatment begins.

(3) *Gamma Knife Treatment Delivery Phase*

54. The treatment delivery phase requires the presence of an authorized user (i.e. the radiation oncologist) and an authorized medical physicist. Before treatment begins, the patient is positioned on the treatment bed and the head frame is attached to the Gamma Knife machine. See Gamma Knife Illustrations, attached as Exhibit 3. As explained above, the Gamma Knife

machine is operated from an adjacent protected control room. The Gamma Knife machine does not move during treatment and is therefore able to aim the beam at the tumor within the brain with a high degree of precision. Depending on the Gamma Knife model and the treatment plan, the whole treatment may be performed without interruption, or it may be broken up into multiple smaller parts throughout the day. The time to perform the treatment delivery varies from 30 minutes to several hours, depending on the complexity of the case. Gamma Knife radiosurgery feels very similar to an MRI or an x-ray; therefore, the treatment is painless and the patient is generally able to go home soon after the treatment is finished.

D. CyberKnife

55. Like Gamma Knife, CyberKnife involves inherent radiation risks that justify strictly regulating the procedure. CyberKnife treatments must be directly supervised by a radiation oncologist who is immediately available to step in and perform the procedure if necessary.

56. Once the treating physicians determine that a patient should receive CyberKnife treatment, a planning sheet containing the patient's diagnosis, the anatomic site to be treated, imaging scans required, number of fractions, positioning of the patient, immobilization devices to be used, and other similar information is signed by the treating physicians. At this time, the patient is scheduled for the procedure. Unlike Gamma Knife machine, which remains stationary during treatment, the CyberKnife machine utilizes robotic technology and moves around the patient throughout the treatment. Additionally, CyberKnife relies on image guidance and tracking software to track and adjust for any patient or tumor movement. For these reasons, CyberKnife does not require a head frame to minimize patient movement and to ensure accurate delivery of radiation. Unlike Gamma Knife, the patient does not need to stay at the hospital

during the planning and treatment phases. Thus, treatments may be spread out over multiple days.

57. The CyberKnife procedure consists of several steps, which are discussed in more detail below: (1) implantation of fiducial markers, if necessary, (2) simulation, (3) treatment planning, and (4) treatment delivery.

(1) *CyberKnife Preparation*

58. When CyberKnife is used to treat tumors in an area of the body other than the brain, small metal fiducial markers may be implanted in the soft tissue before the simulation phase. These implanted metal fiducial markers are used to accurately target radiation from CyberKnife to the patient's treatment site. Implantation of the fiducial markers is usually performed by a surgeon or interventional radiologist as a one-hour outpatient procedure seven to ten days before the simulation.

(2) *CyberKnife Simulation*

59. CyberKnife treatment, like Gamma Knife treatment, begins with a simulation phase, during which a CT scan is performed in order to plan precise delivery of radiation to the tumor. An MRI or PET scan may also be necessary in order for the treatment team to fully visualize the tumor and adjacent critical anatomy. During the simulation phase, a face mask or other immobilization device may be created and used to keep the patient still. The simulation phase generally takes one day, although not a full one, to complete and requires the presence of the radiation oncologist.

(3) *CyberKnife Treatment Planning Phase*

60. As with Gamma Knife procedures, the radiation oncologist, the surgeon, and the dosimetrist or physicist use the results of such scans to create a treatment plan. The images from

the scans are digitally transferred to CyberKnife's treatment planning workstation, where the treating physician determines the exact size, shape, and location of the tumor to be targeted and the surrounding vital structures to be avoided. The radiation oncologist and/or physicist then uses CyberKnife's software to generate a treatment plan. Once the volume and the dose of the electromagnetic radiation are determined, the CyberKnife computer performs millions of calculations to determine the best radiation delivery plan. The treatment planning phase may last anywhere from one to three days, depending on the complexity of the case. Like Gamma Knife, once a plan is developed and approved by the team, the radiation oncologist and surgeon provide the physicist with a signed prescription for the treatment. The physicist verifies the prescription before the treatment begins.

(4) *CyberKnife Treatment Delivery Phase*

61. During the treatment phase, the patient is positioned on the treatment table and x-rays are taken to ensure that the patient is in the proper position. See CyberKnife Illustration, attached as Exhibit 4. Accurate positioning is essential to ensure that the proper areas of the patient are being radiated. Consequences of radiating the wrong area may range from mild skin irritation to organ failure, depending on the area of the body affected and the amount of radiation erroneously delivered. As illustrated by the cases of Mr. Jerome-Parks and Ms. Jn-Charles, any mistake in the delivery of radiation can be deadly.

62. Once the CyberKnife's imaging system acquires the digital x-rays of the patient's position, the information is used to move the linear accelerator on the CyberKnife robot to the appropriate position. The ability of the CyberKnife to move around the patient is considered by some medical professionals to represent a major advancement over frame-based equipment such

as Gamma Knife because this movement allows the CyberKnife machine to radiate tumors from different angles and in areas other than the brain.

63. After the treatment begins, the robot moves and re-targets the linear accelerator at a large number of positions around the patient. At each position, a small radiation beam is delivered. This process is repeated at 50 to 300 different positions around the patient to complete the treatment. At various intervals, the linear accelerator stops and additional pictures of the patient are obtained, allowing the CyberKnife machine to track and compensate for small amounts of patient movement.

64. As with Gamma Knife treatment, the entire CyberKnife treatment feels similar to an MRI or an x-ray and is therefore painless. Usually, the patient can go home immediately upon completion. If the treatment plan calls for fractionated radiotherapy, the patient will return on a separate visit for additional treatments. The radiation oncologist is required to directly supervise the treatment phase, meaning that the radiation oncologist must be immediately available to step in and perform the procedure if necessary.

VI. Background on Medicare, Texas Medicaid, and CHAMPUS/TRICARE Billing and Reimbursement for Stereotactic Radiosurgery

A. Overview of Medicare, Texas Medicaid, AND CHAMPUS/TRICARE

(1) Medicare

65. Medicare is a federally funded health insurance program that provides coverage for individuals age 65 or older and individuals under the age of 65 with certain disabilities. Medicare was created in 1965 under Title XVIII of the Social Security Act.

(2) Texas Medicaid

66. Title XIX of the Social Security Act provides for a federal/state entitlement program known as Medicaid. Medicaid is designed to pay for medical assistance for certain low

income individuals and families. Medicaid is a cooperative venture jointly funded by the federal and state governments to assist states in furnishing medical assistance to eligible needy persons.

67. Each state—within broad national guidelines established by federal statutes, regulations, and policies—(1) establishes its own eligibility standards; (2) determines the type, amount, duration, and scope of services; (3) sets the rate of payment for services; and (4) administers its own program. States have broad discretion in determining which groups their Medicaid programs will cover and the financial criteria for Medicaid eligibility. In order to be eligible for federal funds, however, a state must provide Medicaid coverage to certain individuals who receive federally assisted income-maintenance payments. The federal portion of a state's Medicaid payments—known as the Federal Medical Assistance Percentage (“FMAP”)—is calculated by comparing the state's per capita income to the national average.¹¹

68. As of August 2009, approximately 3.1 million individuals were enrolled in the Texas Medicaid program.¹² The Texas Medicaid program is administered by the Texas Health and Human Services Commission. Since January 1, 2004, Texas Medicaid and Healthcare Partnership (“TMHP”) has administered both the claims processing of Texas Medicaid claims and the Texas Medicaid primary care case management services.

(3) CHAMPUS/TRICARE

69. TRICARE, formally known as the Civilian Health and Medical Program of the Uniform Services (“CHAMPUS”), is a federally funded uniform services health care program for active duty and retired service members, members of the National Guard and Reserve, service members' families, survivors of service members, and certain former spouses of service members. TRICARE provides coverage for radiosurgery services, including the types of

¹¹ 42 U.S.C. § 1396d(b). For Fiscal Year 2009, Texas' FMAP was 59.44%.

¹² Texas Medicaid Enrollment Statistics, <http://www.hhsc.state.tx.us/research/MedicaidEnrollment/ME/200908.html> (last visited Mar. 25, 2010).

procedures performed at Baylor Radiosurgery Center. TRICARE is managed in four separate regions based on geographic location, which are jointly managed by the TRICARE Management Activity and TRICARE regional offices. Humana Military Healthcare Services, Inc. (“Humana Military”) administers the TRICARE South Region, which covers most of Texas.

B. Billing and Reimbursement for Stereotactic Radiosurgery Under Medicare, Texas Medicaid, and CHAMPUS/TRICARE

(1) Medicare Billing and Reimbursement

70. Outpatient hospital services, such as stereotactic radiosurgery, are reimbursed under Medicare Part B and the Hospital Outpatient Prospective Payment System (“HOPPS”). More specifically, the professional components of stereotactic radiosurgery procedures, such as those performed by HealthTexas and TOPA radiation oncologists, are reimbursed under Medicare Part B, and the technical components, such as those performed by Baylor, are reimbursed under HOPPS.

(a) Medicare Part B

71. Medicare Part B covers doctors’ services and outpatient care. Medicare Part B reimburses for a physician’s professional fees relating to stereotactic radiosurgery through a physician fee schedule. The Medicare fee schedule is based on a Resource-Based Relative Value Scale, which is adjusted by the geographic practice cost index, which in turn reflects the variation in practice costs by geographic region. The result is then multiplied by a fixed conversion factor that changes annually.

72. Medicare reimburses for stereotactic radiosurgery procedures for the brain, neck, spine, lung, pancreas, prostate, bone, and liver. Coding for stereotactic radiosurgery typically consists of a series of CPT codes describing the individual steps required, including treatment delivery and clinical treatment management. The codes used for treatment delivery depend on

the energy source used. Gamma Knife and CyberKnife, which use photons, are billed using nonspecific radiation therapy treatment delivery codes that are based on the voltage of the energy source. Codes for treatment delivery primarily reflect the costs related to the energy source used as opposed to physician work.

73. In order for a physician to provide stereotactic radiosurgery services to Medicare patients, the physician must enroll in Medicare by completing form CMS-855I; alternatively, a group practice may enroll by completing form CMS-855B. These forms expressly require providers to certify that they will follow all law, regulations, and program instructions applicable to the Medicare program. Providers also certify that the payment of a claim by Medicare is conditioned upon compliance with those laws, regulations, Medicare program instructions, and the provider's compliance with all applicable conditions of participation in Medicare.

74. Physicians use HCFA 1500 forms to bill their services. By signing and submitting HCFA 1500 forms, physicians attest that they personally performed the services rendered. Specifically, the back of the HCFA 1500 form states:

I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were **personally rendered** by me or were rendered incident to my professional service by my employee under immediate personal supervision, except as otherwise expressly permitted by Medicare or CHAMPUS regulations.

See Medicare Part B HCFA 1500 Form, attached as Exhibit 5 (emphasis added).

(b) Hospital Outpatient Prospective Payment System ("HOPPS")

75. On August 1, 2000, CMS implemented HOPPS, which it uses to reimburse for hospital outpatient services. Reimbursement rates under HOPPS are determined using ambulatory payment classification ("APC") groups. The reimbursement rate for a particular medical service is calculated by multiplying the prospectively established scaled relative weight

for the service's clinical APC by a conversion factor to arrive at a national unadjusted payment rate for the APC. The scaled relative weight for an APC measures the resource requirements of the service and is based on the median cost of services in that APC.

76. To account for geographic differences in prices, the labor portion of the national unadjusted payment rate (60%) is further adjusted by the hospital wage index for the area in which the hospital being paid is located. The remaining 40% is not adjusted.

77. As a condition of participation in Medicare, hospitals must be in compliance with applicable federal laws related to the health and safety of patients.¹³ The hospital must also either be licensed or approved as meeting state or local licensing standards.¹⁴ Furthermore, the hospital must assure that its personnel are licensed or otherwise meet state or local licensing standards.¹⁵ As a practical matter, if a hospital is not licensed, the hospital cannot bill and cannot receive reimbursement from Medicare.

(2) *Texas Medicaid Billing and Reimbursement*

78. Similar to Medicare, the Texas Medicaid program reimburses for stereotactic radiosurgery through a physician fee schedule based on the Texas Medicaid Reimbursement Methodology. The Physician Payment Advisory Committee developed the methodology, which is based on Medicare's Resource-Based Relative Value Scale. The Texas Medicaid Reimbursement Methodology calculates reimbursement by multiplying the total relative value units for each procedure by a fixed conversion factor that changes annually. The Texas Medicaid Reimbursement Methodology also includes "access-based fees" for specific services. The Texas Medicaid Provider Manual includes the physician fee schedules for stereotactic radiosurgery each year.

¹³ 42 C.F.R. § 482.11(a).

¹⁴ 42 C.F.R. § 482.11(b).

¹⁵ 42 C.F.R. § 482.11(c).

79. In order to provide radiosurgery services to Texas Medicaid patients, a radiosurgery center must submit an application to the Texas Department of Health, and, if approved, sign a written agreement to participate in Medicaid. The group must also be enrolled in Medicare.

80. The Texas Medicaid Provider Agreement provides that (1) the provider must comply with all of the requirements of the Provider Manual and all state and federal laws and amendments governing or regulating Medicaid;¹⁶ (2) the provider must certify that claims are submitted in accordance with billing guidelines and procedures promulgated by the Texas Health and Human Services Commission, and that all information in claims date is not only true, accurate, and complete, but can be verified by reference to source documentation maintained by the provider;¹⁷ and (3) the provider must comply with all laws regulating Medicaid fraud and waste, including keeping and maintaining “all records necessary to fully disclose the extent and medical necessity of services provided by the Provider” and “any information relating to payments claimed by the Provider for furnishing Medicaid services.”¹⁸

(3) CHAMPUS/TRICARE Billing and Reimbursement

81. TRICARE reimburses for stereotactic radiosurgery based on a fee schedule referred to as the CHAMPUS National Pricing System (“CMAC System”). TRICARE’s fee schedule is based on the CHAMPUS maximum allowable charge (“CMAC”), also referred to as the TRICARE-Allowable charge. TRICARE uses the same conversion factors utilized by Medicare. Nevertheless, because the formula used by TRICARE is not identical to the one used by CMS to calculate the Medicare fee schedule, TRICARE’s allowable charges for its fee

¹⁶ Texas Medicaid Provider Agreement § I.1.1.

¹⁷ Texas Medicaid Provider Agreement § I.1.3.1.

¹⁸ Texas Medicaid Provider Agreement § I.1.2.3.

schedule differ from those calculated by Medicare. In most cases, the resulting CMAC payments are equal to or higher than Medicare payments made under Medicare's fee schedule.

82. In order for a physician in Texas to be reimbursed on claims to TRICARE, the provider must be certified under TRICARE regulations and have his or her certification status verified by Humana Military. This certification process is initiated when a physician completes the proper application form provided by TRICARE and submits this form to Humana Military. By completing and signing one of these forms, a physician agrees to "abide by the TRICARE payment system concept and the remainder of the certification appearing on all TRICARE claim forms."

VII. Supervision Requirements for Gamma Knife and CyberKnife Procedures

83. Both Gamma Knife and CyberKnife procedures are subject to supervision requirements imposed by the Nuclear Regulatory Commission ("NRC"), Centers for Medicare & Medicaid ("CMS"), and state law. The NRC regulates the medical use of radioisotopes, such as the use of cobalt-60 in Gamma Knife procedures, and has its own regulations regarding the level of supervision that must be provided by an authorized medical physicist and an authorized user. Unlike Gamma Knife, CyberKnife does not require the use of a radioisotope, and thus, is not regulated by the NRC. Instead, Texas requires providers who want to use a CyberKnife to register with the state, and this registration sets forth the required level of supervision of the licensee's CyberKnife procedures. Finally, CMS imposes a direct supervision requirement on all hospital outpatient services, including Gamma Knife and CyberKnife procedures.

A. NRC Regulation of Gamma Knife

(1) Background on NRC and Agreement States

84. The NRC regulates Gamma Knife radiosurgery. The medical use of gamma radiation is prohibited unless it is used in accordance with a license issued by the NRC or an Agreement State, which is a state that has been granted the authority to license and regulate the medical use of radiation.¹⁹ An Agreement State must adopt standards that are *at least as stringent as* the NRC's regulations.²⁰ Furthermore, neither the NRC nor an Agreement State can authorize the medical use of radiation by anyone who fails to observe the safety standards implemented by the NRC or the Agreement State.²¹

85. Texas is an Agreement State. Texas' regulations of gamma stereotactic radiosurgery are found in Title 25, Chapter 289 of the Texas Administrative Code.

86. Anyone who willfully violates, attempts to violate, or conspires to violate certain NRC safety requirements, including the physical presence requirement discussed below, may be subject to criminal penalties.²² Furthermore, if NRC regulations are violated, the NRC is authorized to (1) issue cease and desist orders; (2) issue violation notices; (3) revoke, suspend, or

¹⁹ NRC Regulations, 10 C.F.R. § 35.11. The NRC provides assistance to states expressing an interest in establishing programs to assume NRC regulatory authority under the Atomic Energy Act of 1954. The provisions of the Act provide a statutory basis under which the NRC may relinquish to the states portions of its regulatory authority to license and regulate byproduct materials (radioisotopes), source materials (uranium and thorium), and certain quantities of special nuclear materials. The mechanism for this transfer of authority is an agreement signed by the governor of the state and the Chairman of the Commission. *See id.*

²⁰ 42 U.S.C. § 2021(o)(2). An Agreement State is also free to adopt stricter standards than the NRC regulations.

²¹ 42 U.S.C. § 2111 ("The Commission is authorized to issue general or specific licenses to applicants seeking to use byproduct material for research or development purposes, [or] for medical therapy . . . **The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or who fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission.**") (emphasis added).

²² NRC Regulations, 10 C.F.R. § 35.4002. The Department of Justice ("DOJ") is responsible for determining whether to pursue a criminal investigation following violations of NRC Regulations. *See* NRC AND DOJ, MEMORANDUM OF UNDERSTANDING BETWEEN THE NRC AND DOJ 2 (1988), <http://www.nrc.gov/about-nrc/regulatory/enforcement/moudoj.pdf>.

modify licenses; and (4) impose civil penalties.²³ Essentially, the NRC has the authority to take such action as it deems necessary to protect the public health and safety, including the authority, when appropriate, to take immediate action.²⁴

(2) Physical Presence Requirement

87. In order to protect the safety of patients undergoing radiation therapy, the NRC imposes very specific requirements with respect to Gamma Knife procedures, including the requirement that an “authorized user” (i.e., a radiation oncologist) and an authorized medical physicist must be **physically present** throughout all patient procedures involving the gamma stereotactic radiosurgery unit.²⁵ This physical presence requirement stems from the inherent risks involved in Gamma Knife radiosurgery.²⁶

88. Like the NRC regulations, Section 289.256(hhh)(6)(C) of the Texas Administrative Code provides that “for gamma stereotactic radiosurgery units . . . **an authorized user and an authorized medical physicist [must] be physically present** throughout all patient treatments involving gamma stereotactic radiosurgery units . . .”²⁷

89. The term “physically present” is defined in Section V, “Summary of Changes,” of the 2002 revised Part 35, as published in the *Federal Register* on April 24, 2002.²⁸ Physically present “**means to be within hearing distance of normal voice.**” The NRC has clarified that “normal” means “regular” or “average.”²⁹ A raised voice does not constitute a “normal voice.”³⁰

²³ See NRC Regulations, 10 C.F.R. § 35.4001;

²⁴ NRC AND DOJ, MEMORANDUM OF UNDERSTANDING BETWEEN THE NRC AND DOJ 1 (1988), <http://www.nrc.gov/about-nrc/regulatory/enforcement/moudoj.pdf>.

²⁵ NRC Regulations, 10 C.F.R. § 35.615(f)(3).

²⁶ Medical Use of Byproduct Material, 67 Fed. Reg. 20,355 (Apr. 24, 2002) (to be codified at 10 C.F.R. pt. 35).

²⁷ 25 TEX. ADMIN. CODE § 289.256(hhh)(6)(C) (emphasis added).

²⁸ *Id.*

²⁹ NRC, OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS, NRC REGULATORY ISSUE SUMMARY 2005-23 CLARIFICATION OF THE PHYSICAL PRESENCE REQUIREMENT DURING GAMMA STEREOTACTIC RADIOSURGERY TREATMENTS 2 (2005), <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200523.pdf>.

Furthermore, the use of electronic communication devices—such as walkie-talkies, intercoms, or other devices—to amplify the human voice is not permitted.³¹ Under this definition, mere presence on the hospital grounds or in the general vicinity of the treatment area is clearly insufficient; rather, the radiation oncologist and medical physicist must be within feet of the patient throughout the procedure. Baylor adopted “physical presence” as the standard for supervising Gamma Knife procedures, requiring both an authorized user and an authorized medical physicist to be physically present. *See* Baylor Gamma Knife Guidelines, attached as Exhibit 6.

90. As noted above, the NRC is authorized to enforce its regulations by imposing civil penalties or other sanctions for violations of its safety standards. In 2007, the NRC cited the University of Pittsburgh Medical Center (“UPMC”) for violating the physical presence requirement during Gamma Knife procedures on three separate occasions. On at least one of these occasions, the Gamma Knife treatment was improperly initiated by a neurosurgeon instead of a radiation oncologist. As discussed in more detail below, a neurosurgeon cannot satisfy the physical presence requirement unless the neurosurgeon has completed training and education beyond his or her residency and specialty to qualify as an “authorized user.” Although the NRC issued the citation without imposing a civil penalty, the violation lead to a mediated settlement agreement in which UPMC admitted that it had failed to comply with the physical presence requirement. As a result, the NRC required UPMC to inform others in the industry about the violation and about the importance of the physical presence requirement. As discussed in more

The NRC specifically noted that this did not constitute a departure of the current regulatory requirements, but only served to clarify the meaning of the physical presence requirement. *Id.* at 3.

³⁰ *Id.*

³¹ NRC Frequently Asked Questions About Licensing Medical Uses of Byproduct Material Under Revised 10 CFR Part 35, <http://www.nrc.gov/materials/miau/med-use-toolkit/faqs-part35.html#47> (Meaning of “Physically Present”) (last visited Mar. 25, 2010).

detail below, UMPC's disclosure of its violations to others in the industry, however, did not impact Baylor's decision to disregard the physical presence requirement.

(3) Authorized User Requirements

91. In order for a physician to qualify as an "authorized user" for purposes of the physical presence requirement, the physician must either comply with the NRC or Agreement State's stringent training and education requirements or must otherwise be listed as an authorized user on an approved license or permit.³²

(a) Training and Education Requirements

92. Under Section 35.690 of the NRC Regulations,³³ an authorized user must be a physician, such as a radiation oncologist, who has successfully completed at least three years in an approved radiation therapy program and is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State. A physician may also qualify as an authorized user if he or she completes extensive training and work experience, in the areas of radiation therapy, radiation physics and instrumentation, radiation protections, radiation biology, and mathematics pertaining to the use and measurement of radioactivity. Specifically, the NRC requires such a physician to complete:

- **200 hours of classroom and laboratory training** in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, and radiation biology;
- **500 hours of work experience**, under the supervision of an authorized user, involving areas such as calibration measurements and periodic spot-checks, preparation of treatment plans and calculation treatment doses and times, controls to prevent a medical event involving the use of byproduct material, and implementation of emergency procedures to be followed in the event of the abnormal operation of the medical unit or console; **AND**

³² NRC Regulations, 10 C.F.R. § 35.2; 25 TEX. ADMIN. CODE § 289.256(c)(5)(A).

³³ NRC Regulations, 10 C.F.R. § 35.690.

- **Three years of supervised clinical experience in radiation therapy**, under an authorized user, as part of an approved training program.³⁴

93. Unlike the training and education required to become a radiation oncologist, the training and education required to become a neurosurgeon does not automatically qualify a neurosurgeon to serve as an authorized user because neurosurgeons do not specialize in radiation therapy or complete a residency in radiation oncology. Thus, a neurosurgeon does not qualify as an authorized user *unless* that neurosurgeon meets the NRC's authorized user training and education requirements.³⁵

94. Texas' training and education requirements are the same as those imposed by the NRC.³⁶ In order to be listed as an authorized user on a license or permit, the physician must be qualified to perform Gamma Knife procedures by reasons of training and experience. As under the NRC Regulations, a neurosurgeon does not qualify as an authorized user under the State's regulations unless the neurosurgeon otherwise complies with the training and education or licensing requirements for gamma stereotactic radiosurgery units.

(b) License/Permit Requirements

95. A physician, such as a neurosurgeon, may also be an authorized user if a license granted by the NRC or an Agreement State, such as Texas, identifies the physician as an authorized user.³⁷ A physician cannot be listed as an authorized user on a license or permit

³⁴ *Id.* The physician is also required to obtain written attestation that he or she has satisfactorily completed these requirements and is able to function independently as an authorized user for each type of therapeutic unit for which the individual is seeking to be an authorized user and to receive training in device operation, safety procedures, and clinical use for the types of use for which authorization is sought. *Id.*

³⁵ NRC Frequently Asked Questions About Licensing Medical Uses of Byproduct Material Under Revised 10 CFR Part 35, <http://www.nrc.gov/materials/miau/med-use-toolkit/faqs-part35.html#47> (Gamma Knife Neurosurgeons as Authorized Users) (last visited Mar. 25, 2010).

³⁶ 25 TEX. ADMIN. CODE § 289.256(ttt).

³⁷ NRC Regulations, 10 C.F.R. § 35.2. Section 35.2 defines an authorized user as a physician who is identified as an authorized user on (1) a Commission or Agreement State license that authorizes the medical use of byproduct material or (2) a permit issued by a licensee or permittee that is authorized to permit the medical use of byproduct material. *See also* 25 TEX. ADMIN. CODE § 289.256(c)(5)(A)(ii).

unless the physician actually possesses the training and education necessary to perform Gamma Knife procedures. Section 30.33 specifically provides that an applicant must be “qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property.”³⁸ Only qualified physicians can be listed as authorized users on a license or permit. Typically a neurosurgeon does not qualify as an authorized user and cannot fulfill the physical presence requirement unless the neurosurgeon otherwise complies with the training and education or licensing requirements for gamma stereotactic radiosurgery units.

B. Regulation of CyberKnife by the State of Texas

96. CyberKnife treatments conducted at Baylor are regulated in part by Baylor’s registration with the State of Texas. In order to use radiation machines, like CyberKnife, Texas requires providers to apply for and receive a certificate of registration from the Texas Department of State Health Services.³⁹ Providers that receive a CyberKnife registration are only permitted to use CyberKnife in accordance with the registration, which imposes supervision requirements for CyberKnife procedures. Baylor’s CyberKnife registration with the State of Texas requires:

- (a) a Radiation Oncologist (1) has written a prescription for the treatment, (2) has reviewed and signed the plan for the treatment, and (3) is **immediately available** to respond to problems or emergencies; and
- (b) a licensed Medical Physicist (1) has reviewed the calculations for absorbed dose to the patient, (2) has reviewed the beam and clinical dosimetry, (3) has calibrated the system and tabulated the beam data according to the protocol, and (4) is **immediately available** to respond to problems or emergencies.

See CyberKnife Operating and Safety Procedures at 2, attached as Exhibit 7 (emphasis added).

³⁸ NRC Regulations, 10 C.F.R. § 30.33.

³⁹ *See* 25 TEX. ADMIN. CODE §§ 289.226, 289.229.

97. Baylor's CyberKnife Operating Procedures also provide that "[o]nly a Radiation Therapist (RTT) licensed in the State of Texas . . . or a Physician (MD, DO) licensed to practice in the State of Texas, with CyberKnife Privileges may initiate a radiographic exposure of a patient." Similarly, only a properly licensed radiation therapist or physician "with CyberKnife Privileges may initiate a therapeutic exposure of a patient."

98. Furthermore, the State of Texas requires hospitals to maintain their radiation equipment.⁴⁰ Baylor's registration provides that Baylor Radiosurgery Center cannot perform CyberKnife treatments unless the output radiation dose is spot checked each morning that a treatment is scheduled. A medical physicist must verify the results of the spot checks at least every fifth treatment date. The results of the morning spot checks must be recorded in a log, which must be kept on file at Baylor Radiosurgery Center for not less than three years. See Exhibit 7 at 3–5.

C. Medicare, Texas Medicaid, and CHAMPUS/TRICARE Supervision Requirements for Gamma Knife and CyberKnife Procedures

(1) *Gamma Knife and CyberKnife Procedures Must be Directly Supervised as a Condition of Payment*

99. Medicare, Texas Medicaid, and CHAMPUS/TRICARE require that hospitals providing therapeutic outpatient department services to program beneficiaries meet supervision requirements as a **condition of payment**.⁴¹ Outpatient therapeutic services performed in a hospital, including stereotactic radiosurgery, must be directly supervised.⁴² In fact, in 2008, CMS stated that "it has been our expectation that hospital outpatient therapeutic services are provided under the direct supervision of physicians in the hospital and in all provider-based

⁴⁰ See 25 TEX. ADMIN. CODE § 289.229.

⁴¹ 42 C.F.R. § 410.27 (2002).

⁴² See *id.*

departments of the hospital, specifically both on-campus and off-campus departments of the hospital.”⁴³

100. With respect to the location of the supervising physician, in order to satisfy the direct supervision requirement for outpatient therapeutic procedures performed prior to January 1, 2010, CMS regulations provided that the supervising physician must be **physically present in the department and immediately available to provide direction and assistance throughout the performance of the procedure.**⁴⁴ For outpatient services performed in hospitals on or after January 1, 2010, the regulations provide that the supervising physician must be **on the campus of the hospital and immediately available to provide direction and assistance throughout the performance of the procedure.**⁴⁵ Regardless of the slight modification with respect to the geographic limitations of the supervising physician, however, CMS has *always required* the supervising physician to be *immediately available* throughout the performance of the procedure. According to CMS, to be “immediately available,” **the supervising physician must be available to furnish assistance and direction throughout the performance of the procedure—meaning that the physician must be prepared to step in and perform the procedure, not just respond to an emergency.**⁴⁶

⁴³ 73 Fed. Reg. 68,702–04 (Nov. 18, 2008). Some have attempted to argue that the direct supervision requirement did not always apply to outpatient procedures performed in hospitals because the Health Care Financing Administration, the predecessor to CMS, stated in 2000 that it “assumed” that the supervision requirement was met when procedures were performed in hospitals. Using this language, some argued that the direct supervision requirement did not apply because, in hospitals, staff physicians would always be nearby during procedures. CMS, however, rejected this argument. In 2009, CMS clarified that the physician supervision requirement applied equally to on- and off-campus outpatient services. See 73 Fed. Reg. 41,416 (July 18, 2008) and 73 Fed. Reg. 68,502 (Nov. 18, 2008). Furthermore, CMS later pronounced that its position on the applicability of the physician supervision requirement did not constitute a change in the regulations, but instead only reconfirmed **what the regulations had always required.** See 74 Fed. Reg. 35365 (July 20, 2009) (“We continue to believe that the CY 2009 restatement and clarification made no change to longstanding hospital outpatient physician supervision policies as incorporated in prior statements of policy, including the codified Federal regulations.”).

⁴⁴ 42 C.F.R. § 410.32(b)(3)(ii).

⁴⁵ See 42 C.F.R. § 410.27(a)(1)(iv)(A) (eff. Jan. 1, 2010).

⁴⁶ 74 Fed. Reg. 60,316, 60,580 (Nov. 20, 2009).

101. CMS has stated that a physician is not immediately available, for example, if he or she is performing another procedure or service that he or she could not immediately interrupt to supervise the outpatient procedure. Furthermore, the physician clearly cannot be so physically far away from where the outpatient therapeutic service is being performed that he or she could not intervene “right away.”⁴⁷ In this respect, CMS has reconfirmed that “**immediately available**” means that the physician must be able to respond “**without interval of time.**”⁴⁸

102. Additionally, because the supervising physician must be able to step in and perform the procedure if necessary, **only a physician qualified to perform the procedure may serve as the supervising physician.**⁴⁹ As such, the supervising physician must have, within his or her State scope of practice and hospital-granted privileges, the ability to perform the service or procedure.⁵⁰ In order to perform Gamma Knife and CyberKnife procedures, a physician must meet the State’s training and education requirements or must otherwise be licensed to perform the procedure.⁵¹ Therefore, CMS requires a radiation oncologist (or another physician that possesses the required training and education) to directly supervise and be immediately available to furnish direction and assistance throughout the performance of Gamma Knife and CyberKnife procedures.

103. The importance of the supervision requirement during radiation oncology treatments has been articulated by the American Society for Therapeutic Radiology and Oncology (“ASTRO”):

The entire [series of CPT codes that define the process of care in radiation oncology] requires knowledge and training in the natural history of cancer and

⁴⁷ See 74 Fed. Reg. 60,316 (Nov. 20, 2009).

⁴⁸ See 74 Fed. Reg. 60,316, 60,580 (Nov. 20, 2009).

⁴⁹ ASTRO, MEDICARE’S PHYSICIAN SUPERVISION REQUIREMENTS 2 (Updated Feb. 2010), *available at* <http://www.astro.org/PublicPolicy/WhitePapersAndOtherDocuments/documents/SuperV0210.pdf>.

⁵⁰ *Id.*

⁵¹ See 25 TEX. ADMIN. CODE §§ 289.256(c)(5)(A), (ttt).

certain benign disease processes, radiobiology, medical physics, and radiation safety. There exists a requirement for general medical knowledge that can only be achieved by Board certification in radiation oncology (or equivalent training) to synthesize and integrate the necessary knowledge base to safety and completely render care. **The medical therapeutic application of ionizing radiation is irreversible, may cause significant morbidity, and is potentially lethal. Use of ionizing radiation in medical treatment, therefore, requires direct or personal physician management during each step in the process of care described by the [CPT codes].**⁵²

(2) *Baylor's Published Supervision Guidelines*

104. With respect to Gamma Knife, Baylor has always acknowledged through its official policies that the NRC's more stringent physical presence requirement govern Gamma Knife procedures performed at Baylor Radiosurgery Center rather than CMS's direct supervision requirement. See Baylor Physician Presence Requirement Guidelines, attached as Exhibit 8.

105. Baylor's published guidelines regarding physician supervision during CyberKnife procedures, however, have evolved over the years, with each revision implementing more lenient requirements. Initially, Baylor required the radiation oncologist to be physically present during all CyberKnife treatments. TOPA, however, challenged this supervision requirement because it prohibited them from treating patients at their offices in Sammons Cancer Center during CyberKnife procedures. In an effort to encourage TOPA to again refer CyberKnife patients, Baylor revised its supervision requirements in order to allow radiation oncologist to leave the treatment area; the more lenient supervision requirements, however, directly conflict with the supervision requirements imposed by CMS and the State of Texas. According to Baylor's current CyberKnife supervision guidelines, a radiation oncologist must be physically present throughout the first CyberKnife treatment. For treatments two (2) through five (5), however, the guidelines indicate that the radiation oncologist may leave the treatment area as long as he or she

⁵² The ASTRO/ACR Guide to Radiation Oncology Coding 2009, Appendix G: The Responsibility of the Radiation Oncologist in the Process of Care for Patients Undergoing Radiation Therapy.

“remains available”—which is defined as “the individual is available *on an on-call basis to respond to an emergency*.” *See id.* (emphasis added).

106. Merely being available on an on-call basis, however, does not satisfy the direct supervision requirement because CMS requires the radiation oncologist to be present in the department (prior to 2010) or on the hospital campus (on or after January 1, 2010) and immediately available to step in and perform the procedure—not just respond to an emergency.

VIII. Factual Allegations

A. Background on Relators

(1) Dr. Brian Berger

107. Dr. Brian Berger, a radiation oncologist, is board certified by the American Board of Radiology in Radiation Oncology. With nearly ten years of clinical experience, Dr. Berger has performed hundreds of stereotactic radiosurgery procedures, such as Gamma Knife and CyberKnife. Additionally, Dr. Berger has authored dozens of publications and presentations throughout his career regarding SRS and other forms of radiation therapy.

108. After receiving a Bachelor of Arts in Chemistry from Duke University in 1992, Dr. Berger received a Doctorate in Medicine in 1996 from the University of Texas Southwestern Medical School in Dallas, Texas. Dr. Berger completed an internship in Internal Medicine at the University of Texas Southwestern Medical Center and his Residency in Radiation Oncology at the University of Utah.

109. From 2001 to 2003, Dr. Berger served as an Assistant Professor of Radiation Oncology at the University of Texas Southwestern Medical Center in Dallas, Texas. In this capacity, Dr. Berger served as a full-time general radiation oncologist, specializing in adult and pediatric tumors.

110. From 2004 to 2008, Dr. Berger served as the Co-Founder and Associate Medical Director of Baylor Radiosurgery Center located at Baylor University Medical Center. In this capacity, Dr. Berger assisted in building and designing the \$10 million radiosurgery center, which is equipped with an Elekta Gamma Knife and an Accuray CyberKnife. In his capacity as a radiation oncologist, Dr. Berger performed hundreds of Gamma Knife and CyberKnife procedures at Baylor Radiosurgery Center.

(2) Janice Delp

111. Janice Delp, a radiation therapist with twenty-four years of experience, received her registration in radiologic technology in 1984 from Salem Community Hospital School of Radiologic Technology in Salem, Ohio. Delp attended George Washington University from 1984 to 1989, where she received her registration in radiation therapy in 1985 and her certification in Magnetic Resonance Imaging ("MRI") in 1987. In 1995, the Texas Department of State Health Services certified Delp as a Medical Radiologic Technologist.

112. From 1985 to 1987, Delp served as a Radiation Therapist at the National Cancer Institute in Bethesda, Maryland. In this capacity, Delp was responsible for the set-up and administration of daily therapeutic radiation treatments. After being promoted to Assistant Chief Technologist in 1987 and until 1990, Delp was responsible for the clinical training and supervision of staff radiation therapists.

113. From June 1991 to November 1994, Delp served as a Chief Radiation Therapist at Orlando Cancer Center, Orlando Radiation Care, and Southeast Georgia Regional Medical Center. As the Chief Radiation Therapist at each of these facilities, Delp was responsible for hiring, training, and supervising radiation therapists. Delp was also responsible for the overall supervision of the clinical treatment areas.

114. From November 1994 to November 2004, Delp worked at the University of Texas Southwestern Medical Center in Dallas, Texas as a Senior Radiation Therapist, Chief Radiation Therapist, and Stereotactic Radiation Therapist. In these capacities, Delp was responsible for the scheduling, set-up, and treatment of patients requiring stereotactic radiosurgery. Delp was also responsible for the set-up and delivery of Intensity-Modulated Radiation Therapy (“IMRT”)—an advanced mode of high-precision radiotherapy that utilizes computer-controlled linear accelerators to deliver precise radiation doses to a malignant tumor or specific areas within the tumor.

115. Delp began working at Baylor University Medical Center in November 2004 and was involved in the start-up of Baylor Radiosurgery Center. From 2004 until December 2009, Delp served as a Stereotactic Radiation Therapist and Clinical Coordinator at Baylor Radiosurgery Center. In her capacity as a Stereotactic Radiation Therapist, Delp is responsible for the scheduling, set-up, imaging, and treatment of patients requiring stereotactic radiosurgery. In her capacity as a Clinical Coordinator, Delp coordinated all of the staff and the patient flow for both Gamma Knife and CyberKnife procedures, and was also responsible for billing review. Delp is also a member of the Radiation Safety Committee. In December 2009, Baylor hired a nurse supervisor who took over as Clinical Coordinator. Delp continues, however, to schedule the CyberKnife patients, but she is no longer responsible for scheduling Gamma Knife patients, coordinating the staff, or billing review.

B. Relators’ Observations of Defendants’ Failure to Properly Supervise Stereotactic Radiosurgery Procedures

116. During the course of their employment at Baylor Radiosurgery Center, Dr. Berger and Delp routinely observed violations of both the NRC’s and CMS’s supervision requirements applicable to Gamma Knife and CyberKnife procedures, the supervision requirements in its